UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.*, Plaintiffs and Relator, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	11 Civ. 0071 (PGG)
UNITED STATES OF AMERICA, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO EXCLUDE THE TESTIMONY OF VIRGINIA B. EVANS

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Table of Contents

Table of Authorities

Rules

Other Authorities

The United States of America (the "United States" or the "Government") respectfully submits this memorandum of law in opposition to Defendant Novartis Pharmaceuticals Corporation's ("Novartis"/"NPC") motion to exclude the testimony of Virginia B. Evans.[1]

PRELIMINARY STATEMENT

Virginia B. Evans, the Government's healthcare compliance expert, performed an analysis of Novartis's compliance program during the relevant period as it applied to speaker programs and roundtables (collectively, "Speaker Programs") and concluded that the program was not effective at mitigating Speaker Program-related risks until 2010 because it was not "risk-based." Expert Report of Virginia B. Evans ("Evans Rep."), attached as Exhibit ("Ex.") A to the Declaration of Jennifer Jude, dated October 29, 2018 ("Jude Decl."), at 5. Novartis seeks to preclude Evans from presenting this opinion at trial, arguing that Evans's expert report lacks a methodology and "consists entirely of impermissible factual narration." Memorandum of Law in Support of Defendant Novartis Pharmaceuticals Corporation's Motion to Exclude the Testimony of Virginia B. Evans ("Mem."), at 2, 8. But Evans used the same rigorous methodology that she has applied in countless past compliance program reviews and that is commonly used in the healthcare compliance field—she evaluated each of the seven "Elements for an Effective Compliance Program" described in the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG CPG"), applying her decades of experience in the field as well as guidance about each element provided in the OIG CPG, the PhRMA Code, and other sources. And Evans uses facts from the record solely to explain the bases for her opinions, as required by Federal Rule of Civil Procedure 26(a)(2)(B)(i). Her report

[1] The State of New York and the relator join in this opposition.

does not contain the type of chronology or narration excluded in the cases that Novartis cites in its brief; nor will she present a chronology or narration at trial. Because Evans will provide expert testimony that will aid the jury in navigating the specialized field of healthcare compliance and handily meets all of the requirements of Federal Rule of Evidence 702, Novartis's motion to exclude her testimony should be denied.

ARGUMENT

A. Evans Applied a Reliable Methodology Based on Recognized Sources of Guidance and Her Extensive Experience as a Healthcare Compliance Expert

Novartis's arguments about Evans's supposed lack of a methodology misunderstand the nature of her inquiry and the compliance field generally. Compliance is an experience-based field, not a scientific one. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 467, 474, 479-80 (S.D.N.Y. 2016) (rejecting movant's "attempt to force [regulatory expert's] opinions into the four-factor mold set forth by *Daubert* that governs scientific expert opinions but is not applicable to a non-scientific regulatory expert.") (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999)). Compliance experts determine whether a compliance program is effective by performing a qualitative assessment of its components and whether they are working as they should to minimize non-compliance and legal risk. *See* Deposition of Virginia B. Evans ("Evans Tr."), Jude Decl. Ex. B., at 26:18-28:10, 53:13-24; Deposition of Heidi A. Sorensen, Esq., ("Sorensen Tr."), Jude Decl. Ex. C., at 90:18-91:21, 93:14-94:9, 172:19-173:22. As Novartis's own compliance expert, Heidi Sorensen, testified at her deposition, whether a compliance program is effective is not determined by applying a set formula, but by performing a holistic analysis. *See* Sorensen Tr. 92:6-94:2, 187:20-188:5, 203:9-204:21 ("holistically . . . that's the way I look at these issues").

Contrary to Novartis's assertion that Evans offers no "objective standard for measuring 'effectiveness,'" Mem. at 3, Evans applied the definition of "effectiveness" that is used in the U.S. Sentencing Commission's Sentencing Guidelines for Organizations,[2] and that is commonly accepted in the compliance industry. Evans Tr. 12:10-21. That is, she evaluated whether Novartis's "compliance program does what it's supposed to do in this sense: That it not only sets forth a framework of standards, but those standards are tested . . . to see whether or not in fact they work. So effectiveness is really a function of [whether] the compliance program [is] working." *Id.* at 13.

Evans evaluated whether Novartis's compliance program met this effectiveness standard by considering Novartis's measures with respect to each of the OIG CPG's seven elements: written policies and procedures, the compliance department and officers, training and education, effective communication, monitoring and auditing, investigation and discipline, and corrective actions. *See* Evans Rep. at 3-4. In her report, Evans explains what the OIG CPG says about each element, discusses how Novartis's compliance program addressed that element, and opines as to whether Novartis's actions with respect to that element were effective at mitigating Speaker Program-related compliance risks. In addition to the OIG CPG and the Sentencing Guidelines, Evans's report discusses and cites to the two versions of the PhRMA Code, the Anti-Kickback Statute ("AKS"), the one-purpose rule, and relevant regulations. *See, e.g.*, Evans Rep. at 5 n.8, 5 n.9, 17 n.70; *see also* Evans Tr. at 21:2-20 (stating that she applied standards found in the AKS, the False Claims Act, Sentencing Guidelines, PhRMA Code, and OIG CPG). Evans also cites to

[2] *See* United States Sentencing Commission, Guidelines Manual, May 1, 2001, Ch. 8, "Sentencing of Organizations," accessed October 29, 2018, at https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2001/manual/CHAP8.pdf at § 8A1.2 (Commentary 3(k)).

healthcare compliance literature, including articles published in journals and compliance industry newsletters, *see* Evans Rep. at 11 n.38, 16 n.69, 21 n.93, 41 n.215, 42 n.216, a healthcare fraud treatise, *see id.* at 17 n.70, and other government guidance documents, *see id.* at 41 n.211, 42 n.217, 60 n.342, among other sources.

Evans applied to this case the same methodology that she has applied when considering the effectiveness of other companies' compliance programs. Evans Tr. 26:18-28:10, 32:7-33:14. Her framework, evaluating a compliance program element-by-element to determine whether instances of non-compliance are measured and used for corrective action that improves the program, is widely used in the field.[3] Indeed, Novartis itself used this framework during the relevant period when Novartis's Board of Directors retained a compliance expert to perform a "Compliance Program Effectiveness Review" as required by Novartis's 2010 Corporate Integrity Agreement ("CIA"). NPCLSV00017850, Jude Decl. Ex. D. That expert performed an analysis using the same framework that Evans used and organized his report around the seven elements from the OIG CPG. *See id.* at 854-55, 861. As such, Evans applied a methodology that has the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field," indicating its reliability. *Kumho Tire*, 526 U.S. at 152.

Evans is also permitted to rely on her extensive experience in the healthcare compliance industry as "[i]n certain fields, experience is the predominant, if not sole, basis for a great deal of

[3] Evans's framework has long been the standard approach used in the healthcare compliance field. On April 4, 2003, the Health Care Compliance Association, a healthcare compliance professional organization of which Evans is a member, Evans Rep. at 1 & Appendix A, published "Evaluating and Improving a Compliance Program; A Resource for Health Care Board Members, Health Care Executives and Compliance Officers," available at https://community.hcca-info.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=625acda6-e057-44cd-a223-922458255c5c, last accessed October 29, 2018. This document describes a step-by-step method to measure the effectiveness of a compliance program following the seven elements found in the Sentencing Guidelines and the OIG CPG.

reliable expert testimony." *See* Advisory Committee Notes to Fed. R. Evid. 702 (2000 Amendments); *Kumho Tire Co.*, 526 U.S. at 150 ("[T]he relevant reliability concerns may focus upon personal knowledge or experience."). Courts regularly admit expert testimony based on experience in a specialized field such as compliance. *See, e.g.*, *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004) (court did not abuse discretion in finding expert's testimony reliable based on his knowledge and experience in insurance industry); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 467, 474, 479 (S.D.N.Y. 2016) (denying motion to exclude testimony from three experts regarding Bayer's compliance with FDA regulatory standards); *United States v. Dish Network LLC*, No. 09-3073, 2016 WL 157387, at *4 (C.D. Ill. Jan. 13, 2016) (expert's "reliance on his experience is an appropriate methodology for opining on whether [company's] actions in monitoring and enforcing compliance with telemarketing laws were reasonable or consistent with industry standards."); *Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 931, 934 (D. Minn. 2014) (permitting three experts to testify about Novartis's compliance with FDA regulations and processes based on their experience and specialized knowledge); *Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) (denying motion to preclude expert from testifying about "FDA regulatory requirements and procedures or offering his opinion as to Allergan's compliance therewith").

While Novartis does not challenge Evans's sterling qualifications,[4] it argues that she "cannot rely upon her own experience to say that other compliance-minded companies were

[4] After 25 years as a federal prosecutor, including in various supervisory roles and as the Civil Health Care Fraud Coordinator, Evans spent the last 13 years in the healthcare compliance industry. Evans Rep. at 1 & Appendix A. As a consultant, she managed Independent Review Organizations for clients under CIAs, conducted compliance risk assessments and internal investigations, worked for audit committees and internal audit departments, and wrote and revised companies' compliance policies. *Id.* Evans also created a compliance department for a

concerned about her purported 'risks' during the relevant time period because she is not aware of any companies being concerned about these issues." Mem. at 7-8. But Novartis defines "experience" too narrowly. Evans's opinions about the AKS risks of Novartis's Speaker Programs do not depend on other companies' "concerns" about their own risks. *See* OIG CPG, at 23732 ("The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience).") And contrary to Novartis's assertion that Evans "cannot identify contemporaneous guidelines warning of these risks or even one company that knew of the risks," she in fact does both. *See, e.g.*, Evans Tr. 93:22-97:13, 100:19-102:25, 113:7-13 (identifying guidelines and evidence that Novartis knew of risks).

Novartis's other complaints about Evans's methodology are similarly unavailing.[5] Novartis argues that Evans's methodology is deficient because "it is not clear from the Report which of [her] conclusions relate to actions NPC should have taken as a 'best practice,' versus actions which supposedly rendered its compliance program 'ineffective.'" Mem. at 4. In fact, Evans makes this distinction clear in her report; every time Evans opines that a particular measure constitutes a "best practice," she states exactly that in her report. *See* Evans Rep. at 18, 20, 34, 42, 44 n.228; *see also* Evans Tr. 116:22-117:17, 175:3-13.

large hospital system and served as its Vice President, General Counsel, and Corporate Compliance Officer. *Id.*

[5] Novartis argues that Evans provided a "you know it when you see it" analysis by citing to her use of that phrase in an exchange with Novartis's counsel during her deposition. Mem. at 7 & n.7. But that exchange concerned a topic that Evans did not offer an opinion on in this case—how to tell when a company has a "culture of compliance," Evans Tr. 31:12-16. As such, that testimony has no bearing on whether the opinions that Evans *is* offering in this case are admissible.

Novartis also argues that Evans "recognizes that NPC's compliance program had some strengths, [but] does not explain how the strengths should be measured against the weaknesses to draw a conclusion on effectiveness." Mem. at 4. But Evans's entire report is an explanation of the bases for her conclusion on effectiveness, which is, by its nature, the result of qualitative assessment of each of the elements and how they work in concert to minimize non-compliance. In her report, Evans addresses both the strengths and weaknesses of Novartis's Speaker Programs compliance efforts, describes how Novartis's implementation of each of the elements changed over time, and explains how through various improvements, Novartis's compliance program eventually became risk-based and effective in 2010. *See* Evans Rep. at 5, 7, 8, 19, 20, 39-40, 41-42, 45, 57-58, 60, 65, 68-69. As stated above, the parties' compliance experts agree that there is no set formula for effectiveness.

Novartis also challenges Evans's methodology on the basis that she is "unable to point to any literature stating that [certain] risks," such as the risks posed by repeat attendance or an insufficient number of attendees at Speaker Programs, were risks "that NPC should have been aware of." Mem. at 5. Arguments about whether an expert has cited to sufficient support for a specific point go to the weight, not the admissibility, of an expert's testimony. *Mirena*, 169 F. Supp. 3d at 412 n.6, 420. But in any case, a seasoned compliance professional like Evans does not need to refer to "literature"—although she does, *see* Evans Tr. 82:11-83:3, 96:6-18—to know that practices such as paying a speaker $1500 to speak to an audience of a single HCP or repeatedly hosting Speaker Programs on the same topic for the same HCPs and their friends more than 20 times in a single year, present serious AKS risks. *See* Evans Tr. 98:20-102:25 ("a small group of doctors [going] to 23, 24, 25 events in a year . . . did not make sense to me from an anti-kickback perspective"). Evans cogently explains why such practices present risks in her

report, Evans Rep. at 9-14, *see also* Evans Tr. 80:10-81:8, as did Novartis's own compliance expert in her deposition, *see* Sorensen Tr. 227:9-229:19 (limiting frequency of meals is "to make sure that the purpose of the meal is not to provide . . . something of value to an individual" as "individuals might want to have entertainment more frequently than education"). Evans also cites to evidence showing Novartis's awareness of these risks: its evolving policy of the minimum number of attendees at Speaker Programs, *see id.* at 10-11 n.29-37, and Novartis compliance department employee testimony, emails, and investigation reports discussing repeat attendance, *id.* at 13 n.50-51.[6]

Finally, Novartis argues that the PhRMA Code "expressly contradicts some of [Evans's] 'conclusion.'" Mem. at 6. Novartis gives two examples—Evans's criticism of Novartis for not defining "occasional" in its policies and Evans's criticism of Novartis for permitting certain golf outings. *Id.* Again, this is not a proper *Daubert* argument as it goes to the weight of Evans's testimony, not its admissibility. *Mirena*, 169 F. Supp. 3d at 427. At any rate, in making this argument, Novartis misses that the PhRMA Code sets a floor for pharmaceutical company behavior, not a ceiling. By using the exact language in the PhRMA Code about "occasional meals" in its compliance policies, NPC made its policies comply with the Code itself. But it is Evans's expert opinion that doing that minimal amount was not sufficient for a company whose

[6] Novartis gives as its sole example of Evans purportedly opining about Novartis's state of mind, Evans's statement that "NPC was aware that repeat attendance presented serious compliance risks." *See* Mem. at 10 n.8 (citing Evans Rep. at 14; Evans Tr. 102:16-25). Evans is not offering speculation or "impermissibly embrac[ing] a legal conclusion" about Novartis's intent or motive. *See In re Rezulin Prods. Liab. Litig.* , 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). Rather, Evans is merely explaining that Novartis had information in its possession that demonstrated that repeat attendance presented a compliance risk. *See Mirena*, 169 F. Supp. 3d at 479 (permitting expert to "opine on what documents in Bayer's possession said—in other words, on what Bayer 'knew' in the sense of what information was in its possession" which was not improper "state of mind" testimony).

sales representatives were interpreting "occasional" to allow them to pay for doctors to attend the same programs upwards of 20 times in a single year. *See* Evans. Rep. 13 n.50-51, 65 n.373, 67 n.380. Policies must be tailored to each company's particular risks based on its business operations. *See* OIG CPG, at 23732.

B. Evans Presents Expert Opinions Supported by the Record, Not Factual Narration

Novartis mischaracterizes Evans's report in arguing that it consists entirely of factual narration and should be excluded in its entirety. *See* Mem. at 8, 13. Of course, the fact that Evans offers analysis and opinions about Novartis's compliance program—opinions that Novartis criticizes elsewhere in its brief—belies Novartis's argument that Evans's report is purely factual recitation. And the parts of Evans's report that discuss facts from the record are not mere narration, however, but "reliance on the record [that] is closely tied to the formation of [Evans's] opinions or conclusions," and are thus admissible. *In re Lyondell Chem. Co.*, 558 B.R. 661, 668-69 (Bankr. S.D.N.Y. 2016); *Mirena*, 169 F. Supp. 3d at 478 (granting motion to exclude narrative testimony "insofar as [expert] merely repeats facts, as opposed to *using documents and background to opine on the FDA, the adequacy of Mirena's label and the reasonableness of Bayer's conduct pursuant to FDA regulations*." (emphasis added)).

In its brief, Novartis cites to several cases in which factual narratives were excluded because they did not aid the jury as required by Rule 702. Mem. at 9-10. For example, in *Rezulin*, the court excluded the opinion of an expert who sought to provide a "historical commentary of what happened" during the regulatory review process for the drug at issue. 309 F. Supp. 2d at 551. Similarly, in *In re Fosamax Products Liability Litigation*, which Novartis discusses at length, the court granted Merck's motion to preclude an expert from offering "a narrative history of Fosamax" because "[a]n expert cannot be presented to the jury solely for the

purpose of constructing a factual narrative based upon record evidence."[7] 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (internal quotation marks omitted). And in *Lyondell*, the court precluded an expert from presenting a "21-page 'Chronology'" that was a recitation of facts that were "unrelated to technical or specialized conclusions." 558 B.R. at 668-69. But Evans does not purport to provide a history or chronology bearing any resemblance to those offered by the experts in these cases.

Instead, Evans's report is analogous to the expert testimony that the *Lyondell* and *Fosamax* courts ruled was admissible in the parts of those opinions that Novartis did not cite or address in its brief. For example, although the *Fosamax* court struck the expert's "narrative history of Fosamax," it permitted that expert to present the bulk of her testimony, including her "opinion as to Merck's compliance with general FDA regulatory requirements." *Id.* at 190-92. As the court explained, the expert had "followed an appropriate methodology" by "draw[ing] a conclusion from a set of observations based on extensive and specialized experience" and her assessment "will be helpful to the jury," which "cannot be expected to understand the complex regulatory framework that informs the standards of care in the pharmaceutical industry." *Id.* The expert was permitted to testify about evidence in the record in order to "explain[] the regulatory context in which [the evidence was] created, defin[e] any complex or specialized terminology, or draw[] inferences that would not be apparent without the benefit of specialized knowledge." *Id.* at 192. And in *Lyondell*, while the court did not allow the expert to present his chronology of the record, it allowed him to testify "where [his] record reliance [was] closely tied

[7] The Court does have discretion to allow the presentation of testimony in narrative or summary format if it finds that it would be helpful to the jury. *See In re Yasmin and YAZ (Drospirenone) Marketing Litig.*, No. 03-09-md-02100-DRH-PMF, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) (citing Federal Rules of Evidence 611 and 1006).

to technical conclusions." 558 B.R. at 669. Evans's testimony is admissible for the same reasons that the *Fosamax* and *Lyondell* courts permitted expert testimony—she uses the record to support specialized conclusions that will aid the jury.

At trial, Evans will present her opinions on Novartis's compliance program's efficacy, not a mere timeline of compliance-related events. To do this, she necessarily must discuss the record. For example, Evans must describe Novartis's Speaker Program policies and how they changed over time in order to explain why they were ineffective and to show at what stage and how they eventually became effective. Evans Rep. at 9-20. And where Evans discusses Novartis's auditing and monitoring efforts over the course of the relevant period, that is part and parcel of her analysis of them.[8] *Id.* at 40-59. If Novartis believes that in testifying on these topics Evans is departing from an analysis of the facts into a narration of them, it may object at trial. *See Wells*, 2013 WL 7208221, at *2 ("Defendant may object at trial if Dr. Kessler appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.")

Novartis also argues that Evans improperly "weigh[ed] or assess[ed] the credibility of the evidence." Mem. at 10. Novartis fails to point to examples of Evans actually doing that, however. For example, Novartis cites to Evans's explanation during her deposition that her determination that many of Novartis's Speaker Program policies were ambiguously worded was

[8] Novartis writes that five pages of Evans's report discussed two audits that Novartis conducted in 2008 and 2009 and that the "entire five-page section is factual narration and contains no expert analysis." Mem. at 12. In her report, Evans described the results of these audits, which as the first field audits of Speaker Programs that Novartis performed yielded important results, as background for the reader. *See* Evans Rep. at 51-55. However, Evans will not need to and does not intend to describe the audit to the jury in this level of detail, particularly because the audit report is a document will itself come into evidence as it is a non-hearsay party-opponent statement under Federal Rule of Evidence 801(d)(2), and because several fact witnesses have been deposed about (and may testify at trial about) the audit results.

based on her own reading of those policies as well as deposition testimony from Novartis compliance officials that sales representatives were having difficulty interpreting the policies. Evans Tr. 73:3-75:7. Just because Evans's opinion on that point is consistent with the deposition testimony of certain Novartis compliance officials but not that of Novartis's Martins Putenis, who was responsible for the policies and testified that he believed they were well-written, does not mean she made credibility determinations about the evidence. Mem. at 10 n.8 (citing Evans Tr. at 74:8-75:10). This is not the type of testimony "regarding the credibility of . . . witnesses" that is not permitted. *Highland Capital Mgmt., L.P. v. Schneider*, 551 F. Supp. 2d 173, 180, 182-83 (S.D.N.Y. 2008) ("Guild may not opine as to the credibility of Leonard Schneider, Rauch, RBC employees, or other witnesses"). Evans is not opining that Mr. Putenis (or any other person) is not a credible witness. In addition, it is perfectly acceptable for Evans to have opined that Novartis compliance officials did not adequately "recognize[a particular] risk, or . . . did not describe it adequately to the sales reps," based on their deposition testimony. *See* Mem. at 10 n.8; Evans Tr. 127:19-128:16. This too is not a credibility determination.

Finally, Novartis argues that Evans was selective in which facts she chose to include in her report, Mem. at 11; that she did not explain the basis for her opinion that repeat attendance by doctors at Speaker Programs presented a "serious AKS risk," *id.*; that she relied on documents related to Novartis's financial controls, which Novartis believes "do not have any bearing on NPC's compliance with laws and regulations," Mem. at 12; and that she "often relies on irrelevant or inaccurate information in reaching her 'conclusions'," *id.* Needless to say, the Government disagrees with all of these arguments. But each of them goes to the weight of Evans's testimony, not to its admissibility. *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, No. 09 CIV. 3255, 2012 WL 2568972, at *16-17 (S.D.N.Y. July 3, 2012) ("Patriarch may

appropriately contend that Mason's assessments do not support his conclusion, but those contentions will be presented through cross examination and contrary evidence.") (citing *Olin Corp. v. Certain Underwriters at Lloyd's London*, 468 F.3d 120, 134 (2d Cir. 2006)). Novartis may cross-examine Evans about these issues at trial, but none of these them provides a ground for precluding her from testifying where it is clear that she meets the reliability requirements of Rule 702.

CONCLUSION

For the foregoing reasons, the Court should deny Novartis's motion to exclude the testimony of Virginia B. Evans.

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